Endovascular aortoiliac grafts in combination with standard infrainguinal arterial bypasses in the management of limb-threatening ischemia: Preliminary report

Michael L. Marin, MD, Frank J. Veith, MD, Luis A. Sanchez, MD, Jacob Cynamon, MD, William D. Suggs, MD, Michael L. Schwartz, MD, Richard E. Parsons, MD, Curtis W. Bakal, MD, and Ross T. Lyon, MD, *New York, N.Y.*

Purpose: Occlusive disease of the aortoiliac segment may lead to limb-threatening ischemia, if coexisting disease is present in the femoral, popliteal, or tibial arteries. The combined treatment of severe aortoiliac and infrainguinal disease with standard techniques may be hazardous or contraindicated in patients with multiple previous reconstructions, severe comorbid medical illnesses, or both. This report summarizes the technical feasibility and early results of aortoiliac endovascular stented grafts (ESGs) in combination with conventional surgical reconstructions for the treatment of multilevel arterial occlusive disease.
Methods: Seventeen patients with multilevel aortoiliofemoral limb-threatening occlusive disease had an ESG inserted to treat long-segment occlusive disease followed by a conventional surgical bypass. ESGs originated from the aortoiliac junction (seven) or the common iliac artery (10) and were inserted into the common femoral (nine), superficial femoral (four), or deep femoral (four) artery. ESG lengths ranged from 16 to 30 cm (mean, 21 cm). Conventional surgical bypasses were constructed from polytetrafluoroethylene (15) or saphenous vein (two) and extended to the popliteal (12), tibial (two), or contralateral femoral (three) arteries.
Results: Technical success in graft insertion was achieved in 17 (94%) of 18 attempted ESG procedures. The 1-year primary and secondary cumulative patency rates for ESGs were 94% ± 10% and 100%, respectively, whereas the 1- and 2-year patency rates for the extravascular grafts were 92% ± 10% and 100%, respectively. Four patients had minor postprocedure complications (23%), and no deaths occurred. One patient lost his limb at 16 months because of severe pedal sepsis.
Conclusions: Transluminally placed stented grafts in combination with conventional surgical infrainguinal bypasses are a technically feasible and potentially safe option for the treatment of limb-threatening aortoiliofemoral occlusive disease and have demonstrated encouraging early patency. Long-term follow-up will be necessary before widespread application of this technique is advocated. (J Vasc Surg 1995;22:316-25.)

From the Division of Vascular Surgery, Department of Surgery, and the Division of Interventional Radiology, Department of Radiology (Drs. Cynamon and Bakal), Montefiore Medical Center, The University Hospital for the Albert Einstein College of Medicine, New York.
Supported by grants from the U.S. Public Health Service (HL 02990-02), the James Hilton Manning and Emma Austin Manning Foundation, The Anna S. Brown Trust and the New York Institute for Vascular Studies.
Presented at the Nineteenth Annual Meeting of the Southern Association for Vascular Surgery, Cancún, Mexico, Jan. 25-28, 1995.
Reprint requests: Michael L. Marin, MD, Division of Vascular Surgery, Montefiore Medical Center, 111 East 210th St., New York, NY 10467.

0741-5214/95/$5.00 + 0 **24/6/66338**

Patients who have limb-threatening ischemia caused by atherosclerosis generally have diffuse multilevel disease that often requires treatment above and below the inguinal ligament or at several levels distal to the iliac arteries. These patients are frequently older and more likely to have hypertension, diabetes, and other manifestations of symptomatic atherosclerotic disease when compared with patients with single-level occlusive disease.[1-5] In addition, approximately 12% to 15% of these patients require suprainguinal and infrainguinal procedures to appropriately treat their severe ischemic changes.[6]

Prosthetic arterial bypasses have been the standard treatment for lower extremity ischemia caused by extensive aortoiliac occlusive disease.[6-9] Unfortunately, significant morbidity and mortality may be associated with these procedures, especially in those patients with serious comorbid medical illnesses. In addition, between 10% and 20% of aortofemoral grafts may be expected to develop graft limb thrombosis during a 10-year period, necessitating a secondary aortoiliac reconstruction with additional morbidity.[9-11]

Satisfactory results of an alternative intervention with percutaneous balloon angioplasty have been demonstrated for short (< 5 cm) iliac lesions, predominantly in the common iliac arteries.[12,13] More complex lesions that demonstrate resistance to balloon dilation have also been effectively treated by the insertion of intravascular stents.[14-17] These procedures are associated with limited morbidity and virtually no death and may be offered to medically ill patients who would be at increased risk for surgical reconstruction.

However, in spite of the encouraging results for isolated short stenoses, long-segment disease involving the external iliac arteries does not appear to be effectively treated by dilatation alone.[18] Angioplasty of such extensive arterial occlusive disease frequently results in vessels with diffuse intimal fracturing and dissections that are at high risk of thrombosis.

A new technology combines intravascular stents and prosthetic grafts to form stented grafts that are capable of excluding extensive and complex vascular lesions.[19,20] One of the first clinical applications of this concept to treat extensive occlusive arterial disease was by Volodos et al.[21] in 1986. With a series of self-expanding metallic stents covered by a polyester graft, this group reconstructed a long-segment left iliac artery stenosis by a retrograde femoral artery approach.

This report describes the first series of transfemoral endovascular aortoiliac stented graft reconstructions performed in combination with conventional surgical arterial bypasses to treat a patient population with multilevel aortoiliofemoral occlusive disease undergoing limb salvage.

MATERIAL AND METHODS

Patients. During a 24-month period, 17 patients with limb-threatening ischemia caused by aortoiliac and femoropopliteal occlusive disease were treated with endovascular stented grafts (ESGs) and standard infrainguinal reconstructions. Eleven men and six women whose ages ranged from 43 to 82 years (mean, 64 years) were studied. Two patients had severe ischemic rest pain, whereas the remaining 15 patients had varying degrees of ischemic tissue necrosis. All patients had one or more coexisting medical problems or greater than two failed previous aortofemoral reconstructions (Table I). Pulse volume recordings, ankle/brachial indexes, and aortography with femoropopliteal and tibial runoff views were performed in all patients before and after each intervention.

Table I. Coexisting medical problems in patients undergoing endovascular stent graft procedures and extravascular reconstructions

Comorbidity	*No. of patients*
Acute myocardial infarction	1
Severe coronary artery disease; congestive heart failure	14
Chronic obstructive pulmonary disease	5
Diabetes	8
Renal failure	3
Hypertension	13
Stroke	4
Hostile abdomen/scarred groin*	8

*≥ 2 Previous aortic or groin explorations with and without infection.

Operative technique. All procedures were performed with an open dissection and exposure of the anticipated arterial access site. Based on the overall condition of the patient at the time of the procedure, either general (five), epidural (11), or local (one) anesthesia was selected. Two techniques for arterial recanalization were used to create a wide tract within the diseased iliac arteries. When the contralateral iliac artery was patent, recanalization was carried out by means of a contralateral, percutaneously inserted guidewire, "up and over" the aortic bifurcation, developing a prograde arterial wall dissection plane (Fig. 1). This technique allows for maximal control of arterial inflow and ensures that the recanalization process begins within the native arterial lumen. When the "up and over" approach was not technically feasible, retrograde recanalization was used (Fig. 2). Recanalizations were performed through an occluded artery in six patients and through a diffusely stenotic but patent vessel in 11 patients. Each arterial recanalization was accomplished with a 0.035-inch hydrophilic guidewire and an angled directional catheter (Meditech Corp., Watertown, Mass.). Seventeen of 18 patients underwent successful recanalization with one of the previously mentioned techniques. The only patient who did not undergo successful recanalization underwent an axillofemoral bypass.

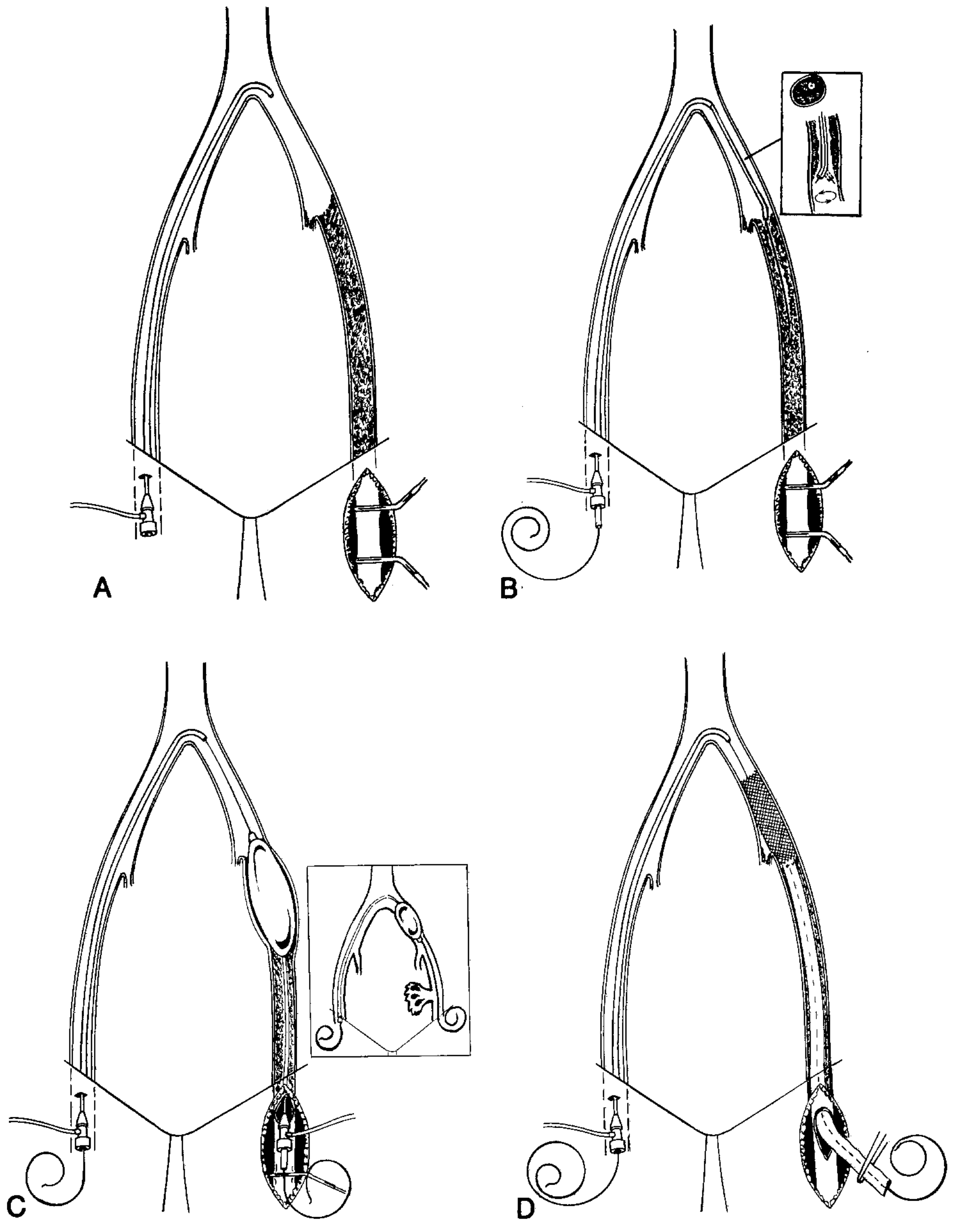

Fig. 1. Surgical procedure of endovascular grafting: "Up and over" technique. For details, see text.

After successful wire recanalization was performed, each iliac artery was dilated along the length of disease with an 8 mm diameter angioplasty balloon (Meditech Corp.). Each stented graft was composed of a Palmaz balloon expandable stent (Johnson & Johnson Interventional Systems, Warren, N. J. [stent-P-294]) that was sutured with four CV-6 polytetrafluoroethylene (PTFE) sutures (W.L. Gore and Associates, Flagstaff, Ariz.) to the proximal end of a 6 mm thin-walled PTFE graft (W.L. Gore and Associates). The proximal 15 mm of the graft that overlapped the stent was devoid of its outer wrap. Each stented graft was then coaxially mounted on an 8 mm × 4 cm balloon angioplasty catheter (Blue Max, Meditech Corp.) and was placed within a single 14F hemostatic introducing sheath with a tapered balloon tip made from an Ultrathin angioplasty balloon (Meditech Corp.). Once the device was fluoroscopically located in a predetermined site, the sheath was partially retracted, permitting proximal stent deployment. The introducer sheath was then completely withdrawn, allowing a redundant portion of the distal end of the graft to emerge from the access vessel.

The distal ESG was then endoluminally or extraluminally anastomosed with one of the techniques illustrated in Fig. 3. These include an endoluminal anastomosis to the femoral artery that is separate (type 1 [Fig. 3, 1]) or included (type 2 [Fig. 3, 2]) as part of the proximal anastomosis of the extraluminal graft extension; an end-to-side anastomosis (type 3 [Fig. 3, 3]) to the superficial femoral artery with an extension to the patent distal arterial tree; an end-to-side anastomosis (type 4 [Fig. 3, 4]) or a side-to-side anastomosis (type 5 [Fig. 3, 5]) to the patent profunda femoris artery with a distal extension; or a direct continuation to the popliteal or infrapopliteal outflow vessel (type 6 [Fig. 3, 6]) bypassing two sequential levels of arterial occlusive disease.

An intraoperative completion angiogram was performed at the conclusion of each endovascular graft procedure. In four (23%) instances mild graft stenoses from inadequate graft expansion or extraluminal compression were detected. All of these lesions were effectively corrected by balloon dilatation of the graft segment (three) or the insertion of a free intragraft stent (one).

ESGs originated from the aortoiliac junction (seven) or the common iliac artery (10) and were inserted into the common femoral (nine), superficial femoral (four), or deep femoral (four) artery with endovascular anastomoses. ESG lengths ranged from 16 to 30 cm (mean, 21 cm). Conventional surgical infrainguinal bypasses were performed immediately after the endovascular aortoiliofemoral reconstructions were successfully completed. Twelve patients received femoropopliteal bypasses with PTFE (eight above-knee, four below-knee), three had femorofemoral bypasses with PTFE, and two had femorotibial reconstructions with reversed greater saphenous veins.

Follow-up studies. All patients underwent preoperative and postoperative pulse volume recordings and a determination of the ankle/brachial index. Postoperative follow-up pulse volume recordings, ankle/brachial indexes, and duplex evaluations were performed at regular intervals (3 months, 6 months, and every 6 months thereafter). In every case a postoperative follow-up arteriogram was performed at 3 days, and additional arteriograms were obtained at any interval where a problem was detected by physical examination or by a noninvasive study.

Anticoagulation. Systemic heparin was administered during each ESG insertion procedure. Long-term anticoagulation was not used.

RESULTS

Technical success in arterial recanalization was achieved in 17 (94%) of the 18 cases. Eleven were totally occluded arterial segments, whereas six were diffusely stenotic. After endovascular aortoiliofemoral reconstruction and conventional surgical bypass were performed, ankle/brachial indexes significantly improved ($p < 0.05$) from a mean of 0.39 to 0.76, and the thigh pulse volume recordings improved from a mean of 9.75 to a mean of 37.8. The 1-year primary and secondary cumulative life table patency rates for all ESGs were 94% ± 10% and 100%, respectively (Fig. 4). Three grafts required a thrombectomy during a 24-month follow-up period. One graft failed because of progression of distal disease, one because of proximal embolic disease, and one because of a proximal common iliac stenosis. All were successfully revised, but one patient still required an amputation because of severe, acute, pedal sepsis.

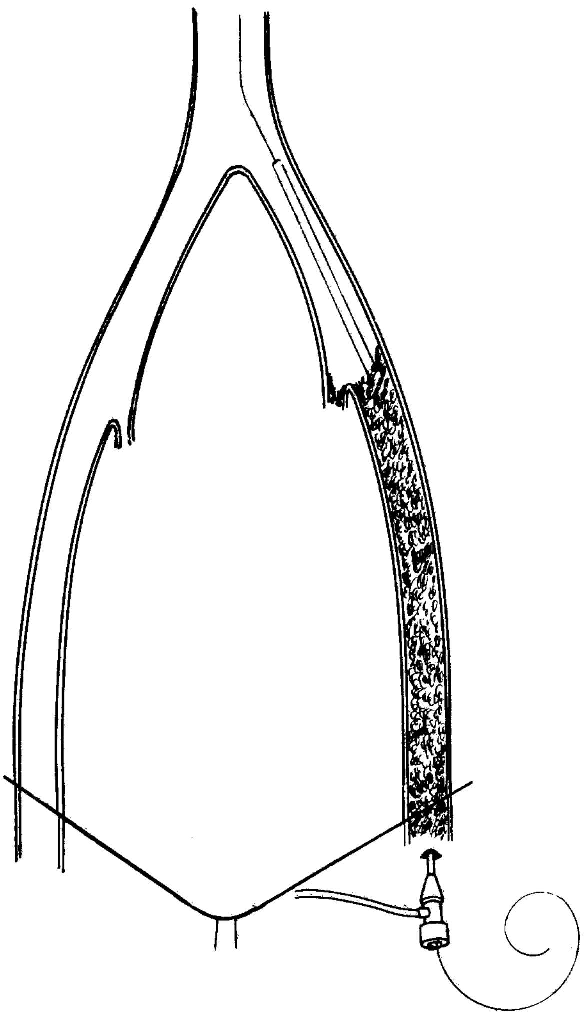

Fig. 2. Surgical procedure of endovascular grafting: Retrograde technique—For details, see text.

The 1-year primary and secondary cumulative life table patency rates for all standard extravascular bypasses were 92% ± 10% and 100%, respectively (Fig. 4). Three extraluminal grafts required revisions:

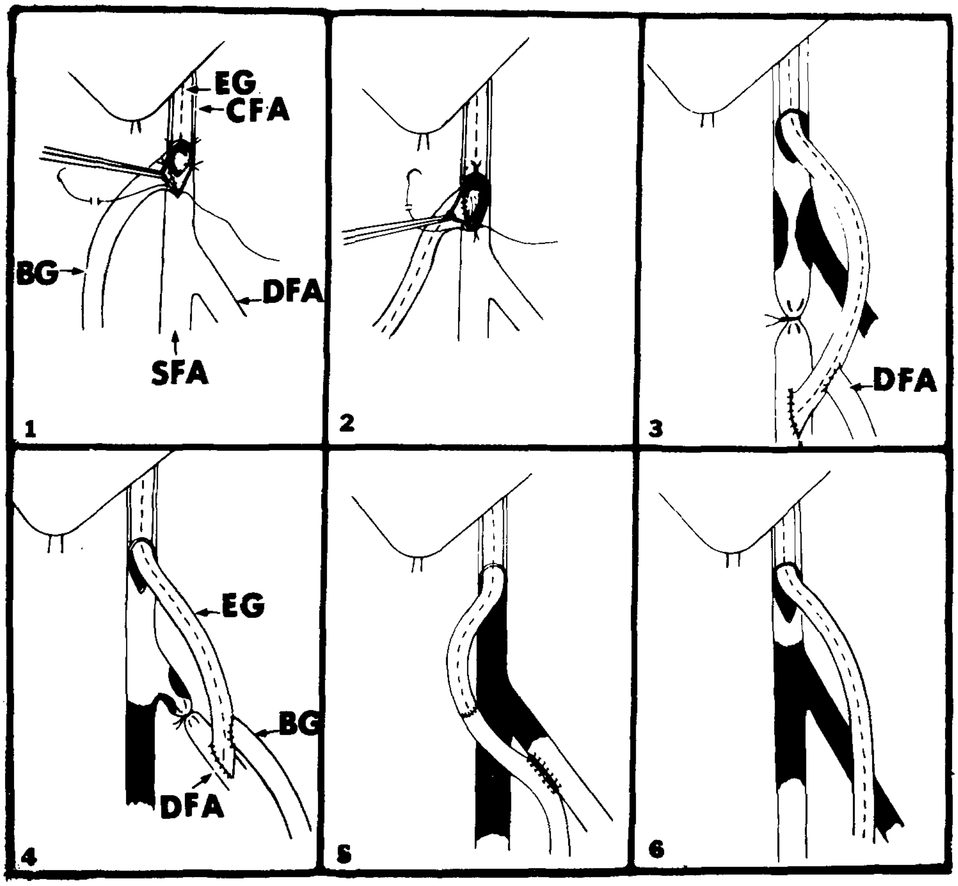

Fig. 3. Distal end of endovascular graft can be anastomosed to patent distal arterial tree in several ways. **(1)** Type 1, endoluminal anastomosis to femoral artery is performed and separate proximal anastomosis of distal extravascular graft is performed to femoral arteriotomy. **(2)** Type 2, intravascular anastomosis and proximal anastomosis of distal extravascular graft are included in single anastomotic closure. **(3)** Type 3, stented graft is brought out through femoral arteriotomy and anastomosed to patent distal superficial femoral artery. From this site distal extension or crossover femorofemoral extension can be performed if necessary. **(4)** Type 4, endovascular graft is brought out through femoral arteriotomy and anastomosed to patent distal deep femoral artery. Extension to distal arterial tree or to contralateral femoral artery can be performed from this graft if necessary. **(5)** Type 5, end of endovascular graft is brought out through femoral arteriotomy and distal graft extension is anastomosed end-to-end to this graft, side-to-side to patent distal deep femoral artery and extended further to distal arterial tree. **(6)** Type 6, endovascular graft is brought out through femoral arteriotomy and can bypass multiple levels of occlusive disease and be anastomosed distally to popliteal or tibial arteries if all femoral vessels are occluded. *EG* represents endovascular graft; *BG* represents distal bypass graft; *SFA* represents superficial femoral artery; *DFA* represents deep femoral artery; *CFA* represents common femoral artery.

one graft failed while the associated ESG maintained normal function, and the other two presented in the failing state with outflow vessel lesions. All three grafts were revised; two required distal extensions and one a thrombectomy.

No deaths were associated with this series. Minor complications occurred in four (23%) instances: one subendocardial myocardial infarction, one lymphocele, and two groin hematomas.

DISCUSSION

In spite of the great successes associated with aortoiliac reconstruction, perioperative morbidity and mortality and late graft limb failures may compromise the long-term results of these procedures.[5,6] In addition, those patients with severe comorbid medical illnesses including cardiac, pulmonary, and renal insufficiency may not be suitable candidates for extensive aortoiliac reconstruction.

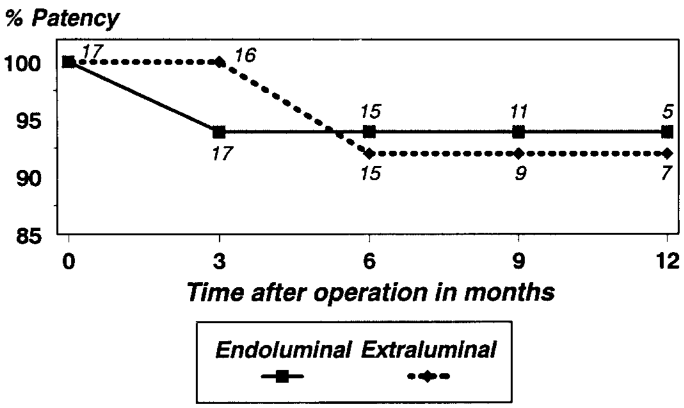

Fig. 4. Twelve-month life-table cumulative primary patency rates for endovascular and extravascular grafts were 94% and 92%, respectively. Number of grafts at each interval are indicated by numbers in table.

Moreover, patients who have severe lower extremity ischemia requiring a multilevel arterial reconstruction for diffuse atherosclerotic disease are at an even higher risk of perioperative complications.

Other less invasive surgical alternatives such as femorofemoral and axillofemoral bypasses have been used to treat such patients with severe aortoiliac disease and significant comorbid medical problems.[22-24] However, these bypasses are not as durable as direct aortic reconstructions, which have patency rates exceeding 80% at 5 years[9,10,25,26] compared with 5-year patency rates of 45% to 65% for femorofemoral and axillofemoral procedures.[27-35] In addition, these extraanatomic bypasses require a surgical intervention on the inflow artery of an asymptomatic limb.

Alternatives to surgical repair of the aortoiliac segment include endovascular therapies such as percutaneous transluminal angioplasty and, in suitable candidates, intravascular stenting.[14,15,36-38] Although there have been encouraging results with these minimally invasive techniques in the management of localized arterial occlusive disease, the treatment of long-segment, complex, occlusive lesions of the aortoiliac segment has not been as promising.[18]

The use of endovascular stented graft technology for the treatment of aortoiliac occlusive disease represents a blending of technologies that include prosthetic grafts, balloon angioplasty catheters, and intravascular stents (Fig. 5). ESGs were conceptualized by Dotter[39] in 1969. Initial clinical reports of endovascular stented grafts for the treatment of arterial occlusive disease at the femoropopliteal and aortoiliac levels have recently been published.[40,41] In addition, the use of similar technology for the treatment of aneurysmal disease and arterial trauma is also rapidly evolving.[19,42-44] This study reports the first series of patients with limb-threatening ischemia caused by multilevel arterial occlusive disease treated with this new and advancing technology in combination with standard bypass procedures.

Endovascular stented grafts have several theoretic advantages. Direct aortic inflow can be obtained, obviating the need to dissect and use an uninvolved artery for inflow (i.e., the contralateral femoral or axillary arteries) and potentially avoiding additional complications and arterial compromise to another extremity. These grafts can be inserted through remote access sites, thereby obviating the need to directly approach a diseased artery. The use of a remote arterial entrance site permits surgical treatment through small incisions without the need to displace and retract abdominal viscera or to perform an extensive retroperitoneal dissection to revascularize an occluded aorta or iliac artery. This minimally invasive approach allows a wide range of anesthetic choices for ESG procedures. Moreover, revascularizations can be carried out through previously unusable, totally occluded arteries. In this series 35% of the arteries that were used as access sites for the recanalization of aortoiliac segments were totally occluded at the time of the procedure. Such occluded arteries serve as entry points into the subintimal plane of the occluded vessel, permitting recanalization wires to dissect within the wall of the occluded artery and into the true lumen of the patent arterial segment. For these occluded segments retrograde entry into the true lumen of the patent proximal vessel after recanalization can be difficult and time-consuming. Recanalization of the occluded segment

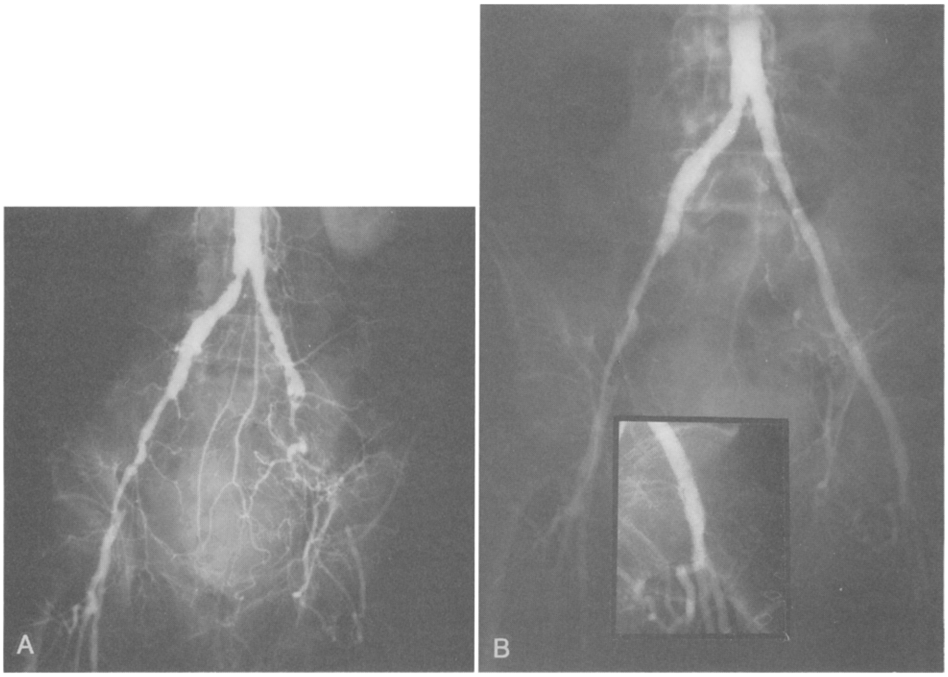

Fig. 5. Sixty-two–year-old woman was admitted with limb-threatening ischemia of left lower extremity. **A,** Pelvic arteriogram shows diffuse iliac disease on both sides with left external iliac artery occlusion. **B,** Iliac artery occlusion was corrected by use of endovascular stented graft from proximal common iliac artery to femoral artery, which was extended to popliteal artery.

in a prograde fashion with the "up and over" technique after contralateral arterial puncture and advancement of the appropriate guidewire and catheter over the aortic bifurcation can lead to easier recanalization from the known patent proximal artery to the surgically exposed outflow vessel. Some additional advantages of this technique are the decreased chance of creating unwanted dissection planes in an arterial segment that will not be relined with a graft and the readily available proximal access for placement of an occluding balloon in case arterial rupture occurs during dilatation of the occluded segment.

Endovascular grafting has been feasible when long, occluded segments are present. When other minimally invasive treatments such as long-segment angioplasty with or without stents are used for long occlusions, results have been poor, presumably because highly thrombogenic flow surfaces with extensive intimal damage have been produced. Endovascular stented grafts provide a single, relatively nonthrombogenic flow surface to completely reline the dilated and frequently diffusely fractured and dissected arterial segments. Because prosthetic vascular grafts in the aortoiliac segment have traditionally had excellent long-term patency rates,[7,8] it might be anticipated that comparable patency rates will be achieved when similar prosthetic grafts are used in the endoluminal position. Other endovascular conduit choices including autogenous saphenous vein are possible.

Several potential disadvantages of endovascular stented grafts exist. The biologic behavior of a prosthetic endovascular graft placed in a diffusely dilated atherosclerotic artery is unknown. Concern exists regarding the potential for arterial recoil after dilatation, disease progression, and smooth-muscle cell proliferation within atheromatous material extrinsic to the endovascular graft. These processes could result in extrinsic compression of the stented graft with subsequent failure. In our series some detectable extrinsic compression of endovascular stented grafts was noted immediately after four (23%) of the 17 aortoiliofemoral grafts were inserted. These compression sites were detected by angiography and did not demonstrate hemodynamic significance. All compressive stented graft lesions were eliminated by either intragraft balloon dilatation (three) or placement of an additional intravascular stent (one). Follow-up studies in these four patients have not demonstrated recurrence of the compressive lesion.

Three of our 17 ESGs required reintervention for a hemodynamically significant failing (two) or thrombosed (one) graft during the 24-month follow-up period of this study. Only one of these demonstrated evidence of a hyperplastic lesion associated with the stented graft. In this instance hyperplasia adjacent to the balloon-expandable stent was responsible for the failing graft. Balloon dilatation of the stent resulted in restoration of normal flow within the endovascular graft and persistent patency. The remaining two grafts that were detected in the failing state had lesions within outflow arteries that were not directly associated with the ESGs.

Technical problems may occur during the process of insertion of an endovascular stented graft for occlusive disease. These devices require long-segment balloon angioplasty of the native vessel before insertion. Such procedures could result in arterial rupture with resulting hemorrhage. Local wire perforation during arterial recanalization was not uncommon. However, arterial rupture during balloon dilatation occurred in one instance. The perforation was managed by proximal balloon occlusion, a technique that was easily accomplished when the "up and over" recanalization procedure previously described was used.

Additional technical limitations relate to the process of arterial recanalization. Because this procedure is performed under fluoroscopic control, an image of the guidewire used for recanalization could be obtained in only two dimensions. This problem has led to difficulty in directing angiographic wires from a patent vessel, through the occluded arterial segment, and back into the patent proximal vessel during retrograde recanalization. The level of difficulty of this portion of the procedure varies from case to case but may be dependent on the chronicity of the arterial occlusion. The "up and over" technique, when feasible, has facilitated guidewire passage through the occluded segment. Technical success was achieved in 94% of the recanalization procedures attempted in this study, and it is expected that with improved three-dimensional imaging technology (intravascular ultrasonography) and improvements in guidewire and catheter instrumentation, the limits of the procedure may be expanded.

Finally, the need to perform an open arteriotomy for each endovascular stented graft procedure is usually a direct result of the overall size and bulkiness of the endovascular stented graft device and carrier system. The ESGs used in this study used standard thin-walled PTFE grafts. These standard grafts were designed for extraluminal use and probably have greater burst strength characteristics than will be needed for endovascular grafts. It is anticipated that with a better understanding of graft and stent attachment device requirements, a smaller profile device may be developed that would be suitable for percutaneous insertion in selected situations. However, open arteriotomies will always represent an excellent alternative for gaining access in those cases in which a total arterial occlusion exists and introduction of the device must be made through this occluded segment.

We have carried out reconstructive surgical procedures in the aortoiliac arterial segment for combined aortoiliac and femoropopliteal occlusive disease by using endovascular techniques in combination with conventional surgical bypasses. In our hands this procedure has proved to be safe and effective with good short-term graft patency rates. In the future we shall increase our experience with this method and analyze the results of a larger number of patients for a longer period of time. Until firm conclusions regarding the performance of this method can be determined, its use must be considered experimental.

REFERENCES

1. Dalman RL, Taylor LM, Jr., Moneta GL, Yeager RA, Porter JM. Simultaneous operative repair of multilevel lower extremity occlusive disease. J VASC SURG 1991;13:211-21.
2. Brewster DC, Perler BA, Robison JG, Darling RC. Aortofemoral graft for multilevel occlusive disease. Arch Surg 1982;117:1593-600.
3. Malone JM, Moore WS, Goldstone J. The natural history of bilateral aortofemoral bypass grafts for ischemia of the lower extremities. Arch Surg 1975;110:1300-6.
4. Royster TS, Lynn R, Mulcare RJ. Combined aortoiliac and femoropopliteal occlusive disease. Surg Gynecol Obstet 1976; 143:949-52.
5. Samson RH, Scher LA, Veith FJ. Combined segment arterial disease. Surgery 1985;97:385-96.
6. Veith FJ, Gupta SK, Wengerter KR, et al. Changing arteriosclerotic disease patterns and management strategies in lower-limb-threatening ischemia. Ann Surg 1990;212:402-14.
7. Brothers TE, Greenfield LJ. Long-term results of aortoiliac reconstruction. J Vasc Interv Radiol 1990;1:49-55.
8. Brewster DC, Darling RC. Optimal methods of aortoiliac reconstruction. Surgery 1978;84:739-48.
9. Poulias GE, Doundoulakis N, Prombonas E, et al. Aortofemoral bypass and determinants of early success and late favourable outcome: experience with 1000 consecutive cases. J Cardiovasc Surg 1992;33:664-78.
10. Szilagyi DE, Elliott JP, Jr., Smith RF, Reddy DJ, McPharlin M. A thirty-year survey of the reconstructive surgical treatment of aortoiliac occlusive disease. J VASC SURG 1986;3:421-36.
11. Nevelsteen A, Wouters L, Suy R. Long-term patency of the aortofemoral Dacron graft: a graft limb related study over a 25-year period. J Cardiovasc Surg 1991;32:174-80.
12. van Andel GJ, van Erp WFM, Krepel VM, Breslau PJ. Percutaneous transluminal dilatation of the iliac artery: long term results. Radiology 1985;156:321-3.
13. Wolf GL, Wilson SE, Cross AP, Deupree RH, Stason WB. Surgery or balloon angioplasty for peripheral vascular disease: a randomized clinical trial. J Vasc Interv Radiol 1993;4:639-48.
14. Liermann D, Strecker EP, Peters J. The Strecker stent: indications and results in iliac and femoropopliteal arteries. Cardiovasc Intervent Radiol 1992;15:298-305.

15. Palmaz JC, Laborde JC, Rivera FJ, Encarnacion CE, Lutz JD, Moss JG. Stenting of the iliac arteries with the Palmaz stent: experience from a multicenter trial. Cardiovasc Intervent Radiol 1992;15:291-7.
16. Hausegger KA, Cragg AH, Lammer J, et al. Iliac artery stent placement: clinical experience with a Nitinol stent. Radiology 1994;190:199-202.
17. Vorwerk D, Gunther RW. Stent placement in iliac arterial lesions: three years of clinical experience with the Wallstent. Cardiovasc Intervent Radiol 1992;15:285-90.
18. Johnston KW. Iliac arteries: reanalysis of results of balloon angioplasty. Radiology 1993;186:207-12.
19. Parodi JC, Palmaz JC, Barone HD. Transfemoral intraluminal graft implantation for abdominal aortic aneurysms. Ann Vasc Surg 1991;5:491-9.
20. Balko A, Piasecki GJ, Shah DM, Carney WI, Hopkins RW, Jackson BT. Transfemoral placement of intraluminal polyurethane prosthesis for abdominal aortic aneurysm. J Surg Res 1986;40:305-9.
21. Volodos NL, Shekhanin VE, Karpovich IP, Troian VI, Gur'ev IuA. Self-fixing synthetic prosthesis for endoprosthetics of the vessels. Vestn Khir (Russia) 1986;137:123-5.
22. Vetto RM. The treatment of unilateral iliac artery obstruction with a transabdominal, subcutaneous, femorofemoral graft. Surgery 1962;52:343-5.
23. Brief DK, Brener BJ, Alpert J, et al. Crossover femorofemoral grafts followed up five years or more: an analysis. Arch Surg 1975;110:1294-9.
24. Ascer E, Veith FJ, Gupta SK, et al. Comparison of axillounifemoral and axillobifemoral bypass operations. Surgery 1985;97:169-74.
25. Sladen JG, Gilmour JL, Wong RW. Cumulative patency and actual palliation in patients with claudication after aortofemoral bypass: prospective long-term follow-up of 100 patients. Am J Surg 1986;152:190-5.
26. Naylor AR, Ah-See AK, Engeset J. Morbidity and mortality after aortofemoral grafting for peripheral limb ischaemia. J R Coll Surg Edinb 1989;34:215-8.
27. Donaldson MC, Louras JC, Bucknam CA. Axillofemoral bypass: a tool with a limited role. J VASC SURG 1986;3:757-63.
28. Christenson JT, Broome A, Norgren L, Eklof B. The late results after axillo-femoral bypass grafts in patients with leg ischaemia. J Cardiovasc Surg 1986;27:131-5.
29. Pietri P, Pancrazio F, Adovasio R, et al. Long term results of extra anatomical bypasses. Int Angiol 1987;6:429-33.
30. Rutherford RB, Patt A, Pearce WH. Extra-anatomic bypass: a closer view. J VASC SURG 1987;6:437-46.
31. Hepp W, de Jonge K, Pallua N. Late results following extra-anatomic bypass procedures for chronic aortoiliac occlusive disease. J Cardiovasc Surg 1988;29:181-5.
32. Piotrowski JJ, Pearce WH, Jones DN, et al. Aortobifemoral bypass: the operation of choice for unilateral iliac occlusion? J VASC SURG 1988;8:211-8.
33. Perler BA, Burdick JF, Williams GM. Femoro-femoral or ilio-femoral bypass for unilateral inflow reconstruction? Am J Surg 1991;161:426-30.
34. Harrington ME, Harrington EB, Haimov M, Schanzer H, Jacobson JH, II. Iliofemoral versus femorofemoral bypass: the case for an individualized approach. J VASC SURG 1992;16:841-54.
35. Brener BJ, Brief DK, Alpert J, et al. Femorofemoral bypass: a twenty-five year experience. In: Yao JST, Pearce WH, eds. Long-term results in vascular surgery. Norwalk: Appleton & Lange, 1993:385-93.
36. Dotter CT, Judkins MP. Transluminal treatment of arteriosclerotic obstruction: description of a new technic and a preliminary report of its application. Circulation 1964;30:654-70.
37. Gruntzig A, Hopff H. Perkutane rekanalisation chronischer arterieller verschlusse mit einem neuen dilatationskatheter modifikation der Dotter-technik. Dtsch Med Wochenschr 1974;99:2502-10.
38. Johnston KW, Rae M, Hogg-Johnston SA, et al. 5-Year results of a prospective study of percutaneous transluminal angioplasty. Ann Surg 1987;206:403-13.
39. Dotter CT. Transluminally-placed coilspring endarterial tube grafts: long-term patency in canine popliteal artery. Invest Radiol 1969;4:329-32.
40. Marin ML, Veith FJ, Panetta TF, et al. Transfemoral stented graft treatment of occlusive arterial disease for limb salvage: a preliminary report. Circulation 1993;88:I-11.
41. Cragg AH, Dake MD. Percutaneous femoropopliteal graft placement. J Vasc Interv Radiol 1993;4:455-63.
42. Marin ML, Veith FJ, Panetta TF, et al. Percutaneous transfemoral insertion of a stented graft to repair a traumatic femoral arteriovenous fistula. J VASC SURG 1993;18:299-302.
43. Marin ML, Veith FJ, Panetta TF, et al. Transluminally placed endovascular stented graft repair for arterial trauma. J VASC SURG 1994;20:466-73.
44. Marin ML, Veith FJ, Lyon RT, et al. Transfemoral stent graft repair of common, internal and external iliac artery aneurysms. Am J Surg (in press).

Submitted Feb. 8, 1995; accepted May 16, 1995.

DISCUSSION

Dr. Jock R. Wheeler (Norfolk, Va.). Assuming all these procedures were done in the operating room, what was the amount of radiation exposure to the patients during the length of the procedure? Also, was this procedure done under IRB control? In spite of the fact that all these devices have been approved, this is certainly an experimental procedure. It was also interesting that 6 mm grafts were used as inflow conduits. In an above-knee femoropopliteal study that we recently presented at a symposium in New York, we showed that 8 mm grafts had a higher patency rate than 6 mm grafts. Taking into account the technical limitations, is a 6 mm graft sufficient? Finally, because the patency rates and costs for this procedure must stand up to those of the "gold standard" of bypass, have you looked at the total cost of these procedures, including the added cost of a secondary procedure, which was necessary in 23% of these cases?

Dr. Luis A. Sanchez. The procedures were performed under an IRB protocol at our institution. All the components you mentioned are FDA-approved for vascular surgery use, although they are not approved for this particular use.

All procedures were performed in the operating room. In regard to the exposure to radiation, the average fluoroscopy time is around 20 minutes. If the recanalization procedure is difficult, such as in the initial cases we performed, then, of course, this time would be longer. However, I do not believe that this is very different from the exposure physicians receive in the radiology suite or from any other fluoroscopic procedure.

The issue of cost is very important and will become even more important as we evaluate new procedures. We are beginning to analyze our data to determine whether, indeed, the cost is reduced and what effect, if any, there is on hospital resource use. Most patients admitted with significant ischemia, gangrene, or ulceration are in the hospital for long periods of time after they undergo revascularization because of wound care and long-term placement problems, not because of the initial intervention. I am not sure if there will be any cost savings with these patients. It is hoped that there will be some improvement in the use of hospital resources as well as morbidity and mortality rates. We do, however, expect a significant improvement in length of stay and cost in patients with aneurysmal and traumatic arterial disease.

The reinterventions necessary in most of these patients were for progression of their arterial disease during the initial 12 to 14 months of follow-up. As with any other bypass, they required a percutaneous intervention or an extension of their reconstruction.

Dr. J. Harold Harrison (Atlanta, Ga.). I am sure I must have missed something. Ordinarily, restoring flow to the deep femoral artery is all that is necessary in the presence of a combination of diseases involving the iliac and femoral arteries. Did I understand correctly that you are routinely restoring flow through the iliac artery or the aorta above and then performing a femoropopliteal bypass at the same time?

Dr. Sanchez. Patients with lower extremity ischemia without foot lesions usually only need the first level of occlusive disease corrected, so that a bypass to the deep femoral artery is usually sufficient. However, all the patients in our group had significant areas of gangrene or ulceration that required straight-line flow to the foot for healing.

Dr. Harrison. How did you know ahead of time? We do not have to do that very often. The deep femoral artery is the best thing in the world.

Dr. Sanchez. We did not know ahead of time. However, these patients had significant ischemia and we did not want to put them through two separate reconstructions. Our decision on whether to perform a sequential reconstruction was based on the presence of poor collateral vessels, a diseased or small deep femoral artery, extremely poor pulse volume recordings, and the size of the lesion that needed to heal.

Dr. Stanley O. Snyder (Norfolk, Va.). In looking at your drawings, it appears that you are bypassing to the deep femoral artery but then ligating it proximally so that you condemn yourself to profunda occlusion if your iliac-to-deep femoral artery bypass fails. That is a little different than what occurs with a routine iliac-to–femoral artery bypass. Also, it seems that you are condemning all the collateral vessels that come into the common femoral and the internal iliac artery.

I hope that one of these days someone will report on what happens to the surgeons during these 20 minutes of fluoroscopy time. I hope the patient is exposed only once or twice.

Dr. Sanchez. We are carefully following the radiation protocols at our institution. We believe that, to prevent any possible long-term injuries, it is very important that all the devices, as well as the protective equipment we use, are the best available.

All patients had an occluded internal iliac artery, which, as you suggested, is a very important collateral to the lower extremity. In addition, most branches of the external iliac artery were also occluded. The grafts to the deep femoral artery were anastomosed end-to-side to maintain the patency of the collateral vessels and their branches.

Dr. Snyder. I hope that, if your grafts do occlude later during follow-up, you will report the amputation levels if they become a factor.

Dr. Sanchez. Absolutely, because that is a very important consideration.

Dr. Alan Lumsden (Atlanta, Ga.). The procedure is a frightening one because it is so easy to perform, you predilate the graft and the graft protrudes from the femoral anastomosis. In those patients in whom you then perform infrainguinal bypass procedures, are you sewing to the predilated portion of the PTFE?

Dr. Sanchez. The area of the graft used for the anastomosis to another graft or the native artery is not predilated. The final reconstruction depends entirely on the patient's anatomy.